

## **SMALLPOX VACCINE INFORMATION STATEMENT (VIS):**

IMPORTANT **INTERIM** SUPPLEMENTARY INFORMATION -- MARCH **31**, 2003

## SMALLPOX VACCINE AND HEART PROBLEMS

There is evidence suggesting that smallpox vaccination may cause cases of heart inflammation (myocarditis), inflammation of the membrane covering the heart (pericarditis), and a combination of these two problems (myopericarditis). Most reported cases occurred in the military where approximately 325,000 doses of smallpox vaccine have been given between December 13, 2002 and March 31, 2003. Of the military cases, most had mild to moderate disease and have recovered. One became severely ill with heart failure on March 27, 2003 and remains hospitalized as of March 31, 2003. All of the military cases were among the approximately 225,000 people who received the vaccine for the first time, occurring at a rate of 1 in 20,000. Experts are exploring this more in-depth.

Heart pain (angina) and heart attack also have been reported in a small number of people following smallpox vaccination. Two of the people who had heart attacks have died. However, it is not known if smallpox vaccination caused these problems or if they occurred by chance alone (heart problems are very common). Experts are investigating this question also.

Reported events are not necessarily caused by the vaccine, and some or all of these events might be coincidental.

As a precautionary step, if you have been diagnosed by a doctor as having a heart condition with or without symptoms you should NOT get smallpox vaccine at this time while experts continue their investigations. These include conditions such as:

- · known coronary disease including:
  - previous myocardial infarction (heart attack)
  - o angina (chest pain caused by lack of blood flow to the heart)
- congestive heart failure
- cardiomyopathy (heart muscle becomes inflamed and doesn't work as well as it should)
- stroke or transient ischemic attack (a "mini-stroke" that produces stroke-like symptoms but no lasting damage)
- chest pain or shortness of breath with activity (such as walking up stairs)
- other heart conditions under the care of a doctor

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## In addition, you should NOT get the smallpox vaccine if you have <u>3 or more</u> of the following risk factors:

- You have been told by a doctor that you have high blood pressure.
- You have been told by a doctor that you have high blood cholesterol.
- · You have been told by a doctor that you have diabetes or high blood sugar.
- You have a first degree relative (for example mother, father, brother, or sister) who had a heart condition before the age of 50.
- You smoke cigarettes now.

These may be temporary exclusions and may change as more information is gathered.

The presence of these conditions in a close contact (such as people you live with) is not a reason for you to defer vaccination.

If you have received the smallpox vaccine, you should see a health care provider right away if you develop chest pain, shortness of breath, or other symptoms of cardiac disease after vaccination.

If you have been diagnosed by a doctor as having a heart condition and have already received the smallpox vaccine, you should contact your heart disease specialist or regular health care provider if you have questions.

For more information, visit <a href="www.cdc.gov/smallpox">www.cdc.gov/smallpox</a>, or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY).

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